

REMARKS

The Office Action of August 22, 2006, has been received and reviewed.

Claims 1-67 were previously pending and under consideration in the above-referenced application. Of these, claims 19-49 were withdrawn from consideration pursuant to an election made in response to a restriction requirement, and have been canceled without prejudice or disclaimer. Claims 1-18 and 50-67, which have been considered, stand rejected.

In addition to claims 19-49, claims 2, 3, 51, and 52 have been canceled without prejudice or disclaimer.

New claims 68-77 have been added.

Reconsideration of the above-referenced application is respectfully requested.

Amendments to the Specification

It is respectfully submitted that the amendments to the specification merely correct typographical and spelling errors and, therefore, do not introduce new matter into the above-referenced application.

While the numbers that appear in paragraph [0031] have been revised, it is noted that paragraph [0032] indicates that specific formulation of the composition disclosed in paragraph [0031] was known as of the filing date of the above-referenced application. Several of the previously provided numbers were erroneous, having been based upon a dosage of four capsules, rather than providing single-capsule amounts. The corrections that have been made to these amounts merely provide more accurate information as to the single-capsule amounts of each element, as evidenced by the enclosed formulation information.

Entry of the revisions to the specification is respectfully requested.

Rejections under 35 U.S.C. § 102

Claims 1-3, 7, 8, 10-15, 17, 50-52, 56, 57, 59-64, and 66 stand rejected under 35 U.S.C. § 102(e) for reciting subject matter that is allegedly anticipated by the subject matter described in U.S. Patent 6,506,413 to Ramaekers (hereinafter "Ramaekers").

A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single reference which qualifies as prior art under 35 U.S.C. § 102. *Verdegaal Brothers v. Union Oil Co. of California*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). The identical invention must be shown in as complete detail as is contained in the claim. *Richardson v. Suzuki Motor Co.*, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989).

Ramaekers describes compositions that include transfer factor and a variety of other components for treating various disorders in animals. While Ramaekers notes that transfer factor molecules may be specific for certain antigens, including antigens of the herpes simplex viruses (col. 1, lines 20 and 21), Ramaekers does not expressly or inherently describe a composition that includes both a blood flow-enhancing component *and* transfer factor specific for at least one pathogen (or an antigen thereof) associated with a treated cardiovascular disorder, as recited in amended independent claims 1 and 50. Therefore, Ramaekers does not describe “[t]he identical invention . . . in as complete detail as is contained in the claim.” *Richardson*, 9 USPQ2d at 1920 (emphasis supplied).

Accordingly, it is respectfully submitted that Ramaekers does not anticipate each and every element of amended independent claim 1, as would be required to maintain the 35 U.S.C. § 102(e) rejections of amended independents claim 1 and 50.

Claims 2, 3, 51, and 52 have been canceled without prejudice or disclaimer, rendering moot the rejections of these claims.

Each of claims 7, 8, 10-15, and 17 is allowable, among other reasons, for depending directly or indirectly from amended independent claim 1, which is allowable.

Claims 56, 57, 59-64, and 66 are each allowable, among other reasons, for depending directly or indirectly from amended independent claim 50, which is allowable.

It is respectfully requested that the 35 U.S.C. § 102(e) rejections of claims 1-3, 7, 8, 10-15, 17, 50-52, 56, 57, 59-64, and 66 be withdrawn, and that each of claims 1, 7, 8, 10-15, 17, 50, 56, 57, 59-64, and 66 be allowed.

Rejections under 35 U.S.C. § 103(a)

Claims 4-6, 9, 16-18, 53-55, 58, and 65-67 have been rejected under 35 U.S.C. § 103(a).

The standard for establishing and maintaining a rejection under 35 U.S.C. § 103(a) is set forth in M.P.E.P. § 706.02(j), which provides:

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

Ramaekers in View of Tokoro or Hennen

Claims 4-6, 9, 16-18, 53-55, 58, and 65-67 are rejected under 35 U.S.C. § 103(a) for being drawn to subject matter that is purportedly not patentable over teachings from Ramakers in view of teachings from U.S. Patent 5,080,895 to Tokoro (hereinafter "Tokoro") or in view of the subject matter taught in U.S. Patent 6,468,534 to Hennen et al. (hereinafter "Hennen").

Ramaekers

The teachings of Ramaekers have been summarized above.

Tokoro

Tokoro has been relied because it purportedly "teaches transfer factor from [an] egg extract of [an] immunized hen." Office Action, page 5. It is respectfully submitted that Tokoro lacks any teaching or suggestion that transfer factor may be obtained from an extract of an egg of an immunized hen.

Rather, the teachings of Tokoro are limited to the presence of a "transfer factor-like component" in eggs that are laid by chickens. Col. 5, lines 4-6, 14-22, and 29; col. 6, line 7.

Further, Tokoro provides that “the immunological functions of the transfer factor-like component . . . are not known” (col. 7, lines 44-47).

One of ordinary skill in the art would readily understand from the disclosure of Dunnick, W., et al., “Lack of Antigen Fragments in Guinea Pig Transfer Factor-like Activity, Clin. Immunol. and Immunopathol. 17: 55-65 (1980), at page 65, that the “transfer factor-like component” mentioned in Tokoro is not transfer factor. A “transfer factor-like” substance, such as the “unknown food factor” described in U.S. Patent 4,402,938 to Collins et al. (*see, e.g.*, Tokoro, col. 7, lines 51-53) or nucleosides, which have molecular weights of less than about 2,000 Da, may cause a non-specific improvement in treated animal’s immune system response. While that improvement could be viewed superficially as similar to the way that immune system would respond to transfer factor, it is generally accepted by those of ordinary skill in the art that these “transfer factor-like” substances are incapable of causing the immune system of a treated animal to elicit a specific response (*i.e.*, a response to a particular antigen).

Transfer factor, in contrast, is known to those of ordinary skill in the art to elicit a specific response from the immune system of a treated animal. Thus, the disclosure of Tokoro clearly indicates to those of ordinary skill in the art that the “transfer factor-like” substance mentioned therein is not transfer factor.

As such, Tokoro cannot be relied upon to show that transfer factor can be obtained from eggs, as would be required to establish a *prima facie* case of obviousness against each of claims 4-6, 9, 16-18, 53-55, 58, and 65-67.

Hennen

It is also respectfully submitted that the Office cannot rely upon the disclosure of Hennen in rejecting any of the claims of the above-referenced application under 35 U.S.C. § 103(a).

In this regard, 35 U.S.C. § 103(c) provides:

Subject matter developed by another person, which qualifies as prior art only under one or more of subsections (e), (f), and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

A priority claim has been made in the above-referenced application to U.S. Provisional Application Serial No. 60/405,358, filed on August 22, 2002. Hennen was not published, and did not issue until October 22, 2002, after the August 22, 2002, filing date of U.S. Provisional Application Serial No. 60/405,358. Therefore, it appears that Hennen qualifies as prior art only under 35 U.S.C. § 102(e).

At the time the invention disclosed in the above-referenced application and in U.S. Provisional Application Serial No. 60/405,358 was made, it was owned by or subject to an obligation of assignment to 4Life Research, LC, as evidenced by the assignment recorded at Reel No. 014922, Frame No. 0844. 4Life Research, LC, is the same party to which Hennen had already been assigned, as indicated by the cover sheet of Hennen.

Therefore, Hennen may not be relied upon in a rejection of any of the claims of the above-referenced application under 35 U.S.C. § 103(a).

It is, therefore, respectfully submitted that a *prima facie* case of obviousness has not been established against any of claims 4-6, 9, 16-18, 53-55, 58, or 65-67, and that each of these claims is therefore allowable under 35 U.S.C. § 103(a).

Ramaekers, Kirkpatrick, and Vercellotti

Claims 9 and 58 have both been rejected under 35 U.S.C. § 103(a) for being directed to subject matter that is allegedly rendered obvious by the subject matter taught in Ramaekers, in view of teachings from U.S. Patent 5,470,835 to Kirkpatrick et al. (hereinafter "Kirkpatrick") and, further, in view of the teachings of Vercellotti, GM, "Microbes, inflammation and atherosclerosis: will old pathology lessons guide new therapies?" Trans. Am. Clin. Climatol. Assoc 112:215-22 (2001) (Abstract) (hereinafter "Vercellotti").

Claim 9 is allowable, among other reasons, for depending directly from independent claim 1, which is allowable.

Claim 58 is allowable, among other reasons, for depending directly from independent claim 50, which is allowable.

Moreover, it is respectfully submitted that Vercellotti teaches away from the purported combination of referenced teachings and, as such, that without the benefit of hindsight that the disclosure and claims of the above-referenced application have provided to the Office, one of ordinary skill in the art wouldn't have had a reasonable expectation that the asserted combination of reference teachings would be successful or been motivated to combine the teachings of Ramaekers, Kirkpatrick, and Vercellotti in the manner that has been asserted. Specifically, Vercellotti teaches that

“microbes contain molecules that mimic host cellular components . . . An immune response to a pathogen may cross react with vessel wall cellular structures. This immune response enhanced by infection may lead to high levels of cross reacting auto-antibodies or auto-aggressive T-cells. . . . Thus, pathogens might contribute to the atherosclerotic process by promoting inflammatory responses.

From this statement, as of the earliest date to which a claim for priority has been made in the above-referenced application, one of ordinary skill in the art could have expected nothing more than for transfer factor to promote an autoimmune response in a treated subject with coronary artery disease and, thus, to do nothing more than increase inflammation in the treated subject. As such, one of ordinary skill in the art wouldn't have had any reason to expect that a composition that includes transfer factor could be useful in treating coronary artery disease, or any motivation to combine the teachings of Ramaekers, Kirkpatrick, and Vercellotti in the manner that has been asserted.

It is, therefore, respectfully submitted that a *prima facie* case of obviousness has not been established against claim 9 or claim 58, and that both of these claims are allowable under 35 U.S.C. § 103(a).

Withdrawal of the 35 U.S.C. § 103(a) rejections of claims 4-6, 9, 16-18, 53-55, 58, and 65-67 is respectfully solicited, as is the allowance of each of these claims.

New Claims

New claims 68-77 have been added.

New claim 68 is an independent claim that recites a composition that includes transfer factor, Vitamin C, niacinamide, an arginine, and a lysine. It is respectfully submitted that none of Ramaekers, Tokoro, Kirkpatrick, or Vercellotti, or any combination thereof, describes, teaches, or suggests such a combination. In particular, none of these references discloses that niacinamide may be included in a composition that also includes transfer factor.

New claims 69 and 70 depend from new independent claim 68. New claim 69 reciting a composition that includes magnesium arginate and magnesium lysate, which is not described, taught, or suggested by any of Ramaekers, Tokoro, Kirkpatrick, or Vercellotti, taken alone or in combination. New claim 70 is directed to a composition that includes Vitamin C and a transfer factor-including preparation in substantially the same amounts, which is not described, taught, or suggested by any of Ramaekers, Tokoro, Kirkpatrick, or Vercellotti when considered alone or in combination.

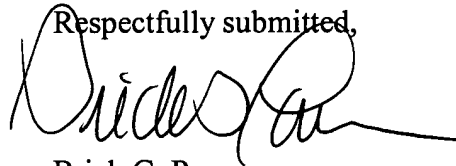
New claim 71 is an independent claim drawn to a composition that includes a transfer factor-including preparation and Vitamin C in substantially the same amounts. Again, none of Ramaekers, Tokoro, Kirkpatrick, or Vercellotti, either separately or collectively, describes, teaches, or suggests such a composition.

New claims 72-77 depend directly or indirectly from new independent claim 71, with each further defining over the subject matter disclosed in Ramaekers, Tokoro, Kirkpatrick, and Vercellotti.

CONCLUSION

It is respectfully submitted that each of claims 1, 4-18, 50, and 53-77 is allowable. An early notice of the allowability of each of these claims is respectfully solicited, as is an indication that the above-referenced application has been passed for issuance. If any issues preventing allowance of the above-referenced application remain which might be resolved by way of a telephone conference, the Office is kindly invited to contact the undersigned attorney.

Respectfully submitted,



Brick G. Power
Registration No. 38,581
Attorney for Applicant
TRASKBRITT, PC
P.O. Box 2550
Salt Lake City, Utah 84110-2550
Telephone: 801-532-1922

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BGP/lmh
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4Life® Transfer Factor™ Cardio™ 4Life

TARGETED NUTRITION FOR CARDIOVASCULAR HEALTH

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Take Aim

The cardiovascular system encompasses the heart, arteries and veins that supply oxygen to vital areas of the body like the brain, the heart and other vital organs. In addition to traditional factors that affect cardiovascular health, healthy homocysteine levels are important.¹

Because of the obvious need for cardiovascular support, 4Life has developed a revolutionary new product to help you take aim at increased health for your heart—4Life Transfer Factor Cardio. 4Life Transfer Factor Cardio targets the key elements important to maintaining a healthy cardiovascular system. Its formulation begins with the unique and scientifically advanced power of Targeted Transfer Factor®.

Independent studies have already demonstrated the superior immune-support capabilities of transfer factors. These messenger molecules educate your immune system and support healthy immune responses, the body's ability to remember past health threats. Now, 4Life has identified a way to focus the power of transfer factors to directly benefit the cardiovascular system. These targeted transfer factors support your body's immune response as it relates to cardiovascular system function. As one of the most innovative products of its time, 4Life Transfer Factor Cardio provides some of the best nutritional support in the health industry today.

4Life Transfer Factor Cardio provides comprehensive support for the cardiovascular system. In addition to providing targeted immune and antioxidant support, it also supports healthy cholesterol levels* and blood vessel health—all necessary for healthy cardiac function.

Key Points

- **Targeted Transfer Factor:** Described as one of the most revolutionary and promising health supplements available today, 4Life Transfer Factor is breaking new ground by actually bringing together the scientific communities with the natural health industry. Transfer factors are tiny messenger molecules that provide highly advanced immune system support; and now, with 4Life Transfer Factor Cardio, you can receive targeted immune support for your cardiovascular system.

An exclusive patent (US Patent 6,468,534) for obtaining specialized transfer factors from egg sources backs this revolutionary new product. The targeted transfer factors found in 4Life Transfer Factor Cardio are developed by managing avian sources in a way that facilitates a healthy immune response within the cardiovascular system. They are then extracted and made available through 4Life's Transfer Factor Cardio to provide the critical immune knowledge needed for effective cardiovascular support.*

This broad and basic patent facilitates the continued formulation of transfer factor products that provide targeted nutritional support. Additionally, this original patent protects 4Life's exclusivity within the transfer factor market and secures our opportunity for expanded patents with future development.

- **Protects and Strengthens:** Because the heart is a dynamic core organ, always pulsating and using oxygen, it's vulnerable to damage from free radicals. Free-radical fighting antioxidants like CoQ10, selenium, copper, zinc and vitamins A, C and E are included in Transfer Factor Cardio to help support the efficiency of the heart, as well as the integrity of vessels and arteries.*
- **Supports Healthy Peripheral Blood Flow:** Proper blood flow contributes to increased energy, decreased blood clotting, better concentration and much more. Ginkgo biloba is a bitter herb that has been shown to support healthy cerebral and peripheral blood flow, as well as circulation and oxygenation to the brain and throughout the entire body.*



DIRECTIONS: Take four (4) capsules daily with 8 oz of fluid.

Serving Size: Four (4) Capsules
Servings Per Container: 30

Supplement Facts

Amount Per Serving	%
Vitamin A (as beta carotene)	2,500 IU 3
Vitamin C (as magnesium dehydroascorbate, ascorbyl palmitate and ascorbic acid)	200 mg 3
Vitamin E (as d-alpha tocopheryl succinate)	100 IU 3
Niacin (as niacinamide)	20 mg 1
Vitamin B6 (as pyridoxine hydrochloride)	2 mg 1
Folate (as folic acid)	400 mcg 2
Vitamin B12 (as cyanocobalamin)	8 mcg 1
Magnesium (as magnesium chloride, dehydroascorbate, arginate and lysinate)	180 mg
Zinc (as zinc arginate)	10 mg
Selenium (as selenomethionine)	50 mcg
Copper (as copper glycinate)	2 mg 1
Potassium (as potassium citrate)	50 mg
Cardio Targeted Transfer Factor	200 mg
A proprietary extract containing Targeted Transfer Factor from egg yolk	
Proprietary Blend	578 mg
Butcher's Broom (root) (22% sterolic heterosides)	
Ginkgo biloba (leaf) (24% ginkgo flavone glycosides, 6% terpene lactones)	
Hawthorn (flower and leaf) (1.8% rutin)	
Garlic (deodorized clove)	
Coenzyme Q10	
Red Rice Yeast Extract	
Resveratrol (from Polygonum cuspidatum)	
Ginger Oil	
*Reference Daily Intakes (RDI)	
**Daily Value (DV) not established	
Other Ingredient: gelatin capsule	

Ordering Information

Item # 21002 - 120 ct/bottle

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4Life® Transfer Factor™ Cardio™

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Key Points continued . . .

- **Maintains Elasticity of Blood Vessels:** Vessel elasticity is necessary to ensure that vitally-needed nutrients and oxygen reach the heart. Arginate is one ingredient that has been shown to support proper function of the inner lining of the blood vessels and the production of nitric oxide, the agent in your body that widens blood vessels and promotes proper blood flow. In addition, magnesium, potassium and vitamin C have been included for their ability to support flexibility and elasticity of blood vessels, and therefore promote healthy blood pressure levels.†*
- **Supports Healthy Homocysteine Levels:** Homocysteine is an amino acid produced by the body that has shown higher potential of being correlated with heart health than cholesterol. Current research indicates that getting enough B vitamins, especially folic acid, B6 and B12, and antioxidants such as selenium, copper, zinc and vitamins A, C and E, is highly effective in supporting healthy homocysteine levels.*
- **Supports Healthy Arteries and Veins:** Ascorbic acid, niacinamide, hawthorn, resveratrol, garlic, lysine and red rice yeast extract also work to support healthy arteries and veins by supporting proper circulation and healthy cholesterol levels.†*

Technical Points

- Transfer factors are unique messenger molecules that educate your immune system and provide the vital information it needs to recognize and respond effectively to potential threats.
- Co-enzyme Q10 has properties potentially beneficial for strengthening cell membranes, and is also a powerful antioxidant.
- Red rice yeast extract contains a number of naturally occurring compounds known as monacolins. Monacolins are known to inhibit the activity of an enzyme in the liver, which is needed to produce cholesterol. This mechanism allows red rice yeast extract to support healthy serum cholesterol and lipid levels.²
- Butcher's Broom is an herb shown to help improve and strengthen capillary fragility.

1. Ngeh, J., V. Anand, et al. (2002). "Chlamydia pneumoniae and Atherosclerosis—what we know and what we don't." Clin Microbiol Infect 8(1):2-13.

2. Heber D, Yip I, Ashley JM, et al. Cholesterol-lowering effects of a proprietary Chinese red-yeast-rice dietary supplement. Am J Clin Nutr. 1999;69:231-236.